Supplement

Fabius family

WARNING

To properly use this medical device, read and comply with the instructions for use and this supplement.

Anesthesia workstation Software 3.n

Supplement to the instructions for use

Device	Part number	Edition
Fabius Tiro	9038686	Up to 7. Edition
Fabius GS *premium*	9038923	Up to 7. Edition
Fabius MRI	9039036	Up to 8. Edition
Fabius *plus*	9039054	Up to 4. Edition
Fabius *plus* XL	9052882	Up to 1. Edition

- Keep this supplement with the instructions for use of the medical device.

The supplement updates the information of the instructions for use in the following chapters:

Definition of target groups

For this product, users, service personnel, and experts are defined as target groups.

These target groups must have received instruction in the use of the product and must have the necessary training and knowledge to use, install, reprocess, maintain, or repair the product. The target groups must understand the language of the present document.

The product must be used, installed, reprocessed, maintained, or repaired exclusively by defined target groups.

Users

Users are persons who use the product in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the product.

Service personnel must be trained in the maintenance of medical devices and install, reprocess, and maintain the product.

Experts

Experts are persons who perform repair or complex maintenance work on the product.

Experts must have the necessary knowledge and experience with complex maintenance work on the product.

For your safety and that of your patients

Product-specific safety information

The following warning statements have been added:

WARNING

Risk of device failure

The device can fail if the power supply is interrupted.

Always connect the device on an uninterruptible power supply.

WARNING

Risk of malfunction

Unallowed modifications to the medical device lead to malfunctions.

This medical device may not be changed without permission from Dräger.

WARNING

Risk of not hearing the alarm tone

Dräger recommends that the user remains in the vicinity of the anesthesia workstation. This facilitates fast recognition and response in the event of an alarm.

- **During therapy directly in front of the device.**
- **When preparing for therapy within a distance of up to 4 meters (13 feet).**

WARNING

Risk of crushing

Movable device parts or attached components may cause crushing due to clamping. Pay special attention to edges, movable parts, and corners when working with the following components:

- **Breathing system cover**
- **Drawers**
- **Extensible writing tray**
- **Swivel arms for mounted devices**
- **Accessories such as gas cylinders, vaporizers, CLIC absorber, and CLIC adapter**

Application

Intended use

The following warning statements have been added:

WARNING

Risk of patient injury

In accordance with the general safety standards for anesthesia systems, additional monitoring of the concentrations of CO_2 and anesthetic agent is required.

WARNING

Risk of explosion

This medical device is neither approved nor certified for use in areas where oxygen concentrations greater than 25 Vol%, combustible or explosive gas mixtures are likely to occur.

WARNING

Risk of patient injury

All data transferred via the MEDIBUS interface are for information only and must not be used as the sole basis for diagnostic or therapeutic decisions. The data accessible via this interface are not intended for use with a distributed alarm system in accordance with IEC 60601-1-8:2012 (in the sense of remote monitoring).

Overview

Symbols

Symbol	Explanation	Symbol	Explanation
	Warning! Strictly follow these instructions for use		Relative humidity
	Label on device surfaces where the risk of tipping is increased by e.g., leaning on or against the surface or pushing		Atmospheric pressure
	Storage temperature		Do not use if package damaged

Operating concept

Color coding of the gas supply

The table has been deleted

The standardized color coding specified in ISO 5359 / ISO 32 / ISO 5360 is used for anesthetic agents and medical gases.

The colors for O_2, Air, and N_2O are adapted in accordance with the locally applicable standard.

Assembly and preparation

Preparation

The following warning statements have been added to the indicated chapters:

Activating the battery

WARNING

Risk of device malfunction

If the battery is not sufficiently charged and the mains power supply fails, operation cannot be maintained long enough.

Before first operation or after storage, charge the battery for at least 8 hours.

WARNING

Risk due to reduced power supply from the internal battery

Batteries are wear parts. The capacity of the battery diminishes with the period of use.

Check the functional state of the battery by performing preventive maintenance on a regular basis.

Connecting to the mains power supply

WARNING

Risk of electric shock and device malfunction

If the device is connected to a power socket with incorrect mains voltage or without a protective ground, the user can be injured and the device damaged.

Only connect the power cable to power sockets with a protective ground, see "Technical data".

NOTE

The mains plug must be freely accessible so that the power supply to Fabius can be quickly interrupted in the event of device failure.

Auxiliary power sockets

WARNING

Risk of electric shock

The connection of devices to auxiliary power sockets can lead to an increased leakage current. If the protective ground of one of these devices fails, the leakage current may rise above the permissible values.

- **Only connect with the approval of the respective device manufacturer.**
- **Have the leakage current checked by service personnel.**
- **If the permissible value is exceeded, use a mains power socket on a wall instead of the auxiliary power socket of the device.**

WARNING

Risk of device malfunction

If the mains power fails, devices connected to the auxiliary power sockets are not supplied from the uninterruptible power supply.

- **Do not connect any life-supporting devices to the auxiliary power sockets of the anesthesia workstation.**
- **Ensure an alternative power supply for connected devices.**

Operation

Ventilation

ManSpont ventilation mode

The following warning statement has been added:

WARNING

Risk of excessively high airway pressures

If the ventilator fails, the device switches into the *ManSpont* ventilation mode.

The APL valve should also be set to a pressure limitation value suitable for the patient when using automatic ventilation modes since in case of a ventilator failure the patient must be ventilated manually.

Safety functions of the ventilator

The following warning statement has been added:

CAUTION

Risk of patient recovering consciousness

If the gas supply fails completely, further operation of the anesthesia machine takes place with gas supply with ambient air. Anesthetic agents are no longer delivered and the inspiratory anesthetic gas concentration in the breathing gas decreases.

Monitor the gas mixture carefully and use intravenous anesthetic agents if need be.

When changing patients

The following warning statement has been added:

WARNING

Risk due to incorrect settings

For anesthesia machines within the same care area, different standard alarm limits or ventilation settings might be configured. The user must observe the following points:

- **Make sure that the values set for new patients are appropriate.**
- **Make sure that the alarm system is neither rendered useless by setting extreme values for the alarm limits nor deactivated by switching off the alarms.**
- **Check the start settings for alarms and alarm settings each time the ventilation mode is changed.**

Configuration

Accessing the alarm log

The following text is added:

The alarm log lists all alarm messages, together with their respective date and time.

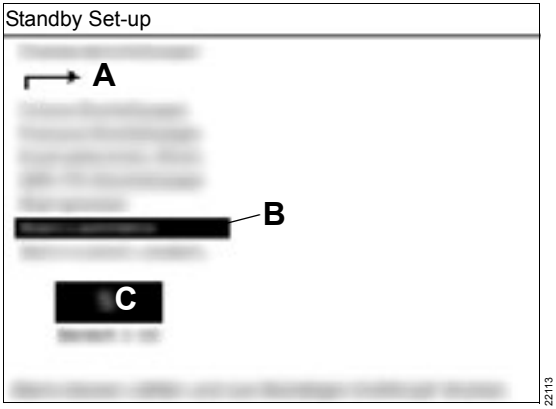
A maximum of 100 entries is saved.

The oldest entries will be overwritten if the storage capacity is reached.

Standard settings in standby setup

The label for the alarm volume setting has been changed to ***Minimum Alarm Volume***.

Minimum alarm volume



1 Select ***Minimum Alarm Volume*** (B) and confirm.

The current minimum alarm volume (C) is displayed on the screen.

2 Set the new minimum alarm volume to a value between 1 (minimum) and 10 (maximum) and confirm.

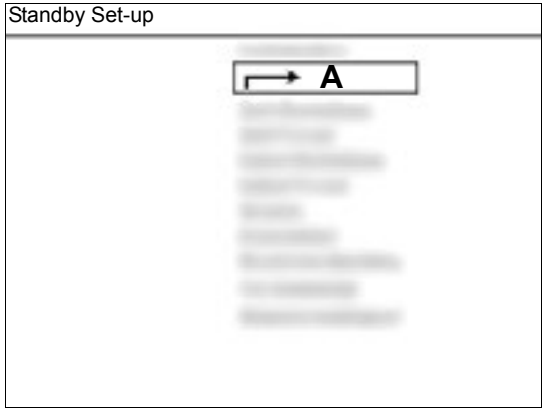
Range: ≥ 45 dB(A) to ≤ 85 dB(A)

The window is closed, the cursor is on the input arrow (A).

Configuration in standby setup

The alarm tone sequence setting has been removed. Only the default alarm tone sequence is used for the alarm tone sequence.

1 On the ***Standby Set-up*** screen, select ***Configuration*** and confirm.



The screen with the configuration settings opens.

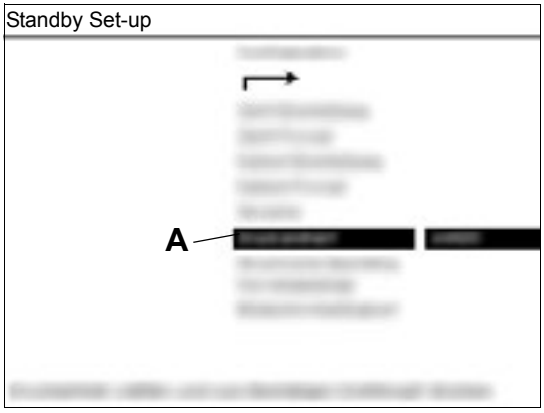
The following settings can be changed:

– ***Time Set***
– ***Time Format***
– ***Date Set***
– ***Date Format***
– ***Language***
– ***Pressure Unit***
– ***Acoustic Confirmation***
– ***Waveform Display***
– ***Display Background***

- To return to the ***Standby Set-up*** screen, select the input arrow (A) and confirm.

An additional unit has been added to the following setting:

Pressure unit



1 Select ***Pressure Unit*** (A) and confirm.

The following units can be selected:

– ***hPa***
– ***cmH2O***
– ***mbar***
– ***kPa***

2 Select new unit and confirm.

The window is closed.

Configuration during operation

Accessing the alarm volume

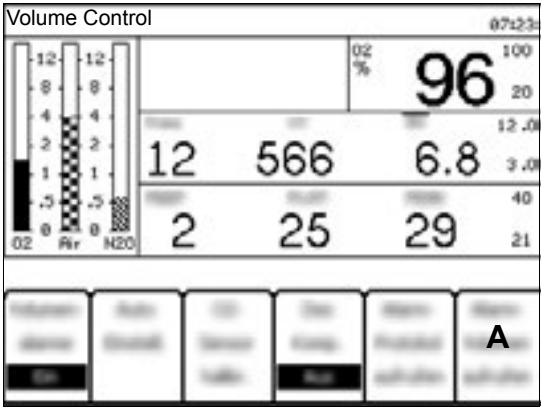
The following warning and text are added to the chapter:

WARNING

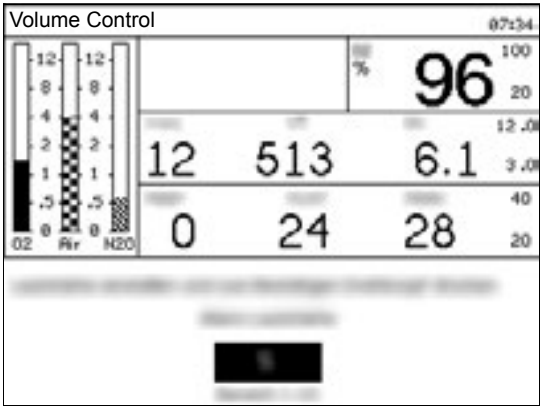
Risk of not hearing the alarm tone

When operating in a loud environment, the acoustic alarm signals may not be heard.

Always set the alarm tone to a sufficient volume.



1 Press the ***Access Alarm Volume*** softkey (A).



2 Set the new alarm volume to a value between 1 (minimum) and 10 (maximum) and confirm.

The lower value is limited to the setting in the standby configuration.

The pressure waveform and the softkeys are displayed again.

Maintenance

Overview

The following warning statement has been added:

WARNING

Risk of fire

When replacing the battery, short-circuits or excessive temperatures can occur, resulting in fire or explosion.

The battery must only be replaced by experts.

Technical data

Alarm tone sequence IEC

The following data are added to the chapter:

Sound pressure level L(A) of the alarm tones at the user's operating location, measured in accordance with IEC 60601-1-8

		Fabius GS Premium	**Fabius Tiro**	**Fabius plus**	**Fabius Plus XL**	**Fabius MRI**
Alarm volume (high priority)	Adjust-able from	approx. 52 dB(A) to approx. 64 dB(A)	approx. 60 dB(A) to approx. 73 dB(A)	approx. 57 dB(A) to approx. 70 dB(A)	approx. 48 dB(A) to approx. 62 dB(A)	approx. 52 dB(A) to approx. 64 dB(A)
Alarm volume (medium priority)	Adjust-able from	approx. 48 dB(A) to approx. 60 dB(A)	approx. 50 dB(A) to approx. 63 dB(A)	approx. 52 dB(A) to approx. 64 dB(A)	approx. 44 dB(A) to approx. 59 dB(A)	approx. 44 dB(A) to approx. 57 dB(A)
Alarm volume (low priority)	Adjust-able from	approx. 43 dB(A) to approx. 56 dB(A)	approx. 50 dB(A) to approx. 60 dB(A)	approx. 49 dB(A) to approx. 62 dB(A)	approx. 40 dB(A) to approx. 53 dB(A)	approx. 42 dB(A) to approx. 56 dB(A)

Characteristics of additional acoustic signals

The following data are added to the chapter:

	Characteristic	Volume				
		Fabius GS Premium	**Fabius Tiro**	**Fabius plus**	**Fabius Plus XL**	**Fabius MRI**
Warning signal for low oxygen supply pressure	Continuous tone, 10 s, adjustable from	approx. 55 dB(A) to approx. 68 dB(A)	approx. 56 dB(A) to approx. 69 dB(A)	approx. 61 dB(A) to approx. 74 dB(A)	approx. 48 dB(A) to approx. 61 dB(A)	approx. 40 dB(A) to approx. 53 dB(A)
Time exceeded when changing ventilation mode	3 tones, adjustable from	approx. 46 dB(A) to approx. 56 dB(A)	approx. 50 dB(A) to approx. 61 dB(A)	approx. 46 dB(A) to approx. 57 dB(A)	approx. 41 dB(A) to approx. 51 dB(A)	approx. 31 dB(A) to approx. 42 dB(A)
Confirmation of selection using rotary knob	Single tone when rotary knob pressed	approx. 51 dB(A)	approx. 52 dB(A)	approx. 55 dB(A)	approx. 56 dB(A)	approx. 47 dB(A)
Power supply failure (mains power supply and battery)	Continuous tone	approx. 57 dB(A) at maximum alarm volume	approx. 61 dB(A) at maximum alarm volume	approx. 56 dB(A) at maximum alarm volume	approx. 59 dB(A) at maximum alarm volume	Only the red LEDs in the alarm LED bars will be flashing
Selection of alarm volume	Single tones per level	(Corresponds to alarm volume)				
Tesla sensor	Single tones sound if Fabius is in a magnetic field >40 mT.	Not applicable				approx. 52 dB(A)

Essential performance characteristics

The following text has been added:

The essential performance characteristics comprise:

– Supplying the anesthesia workstation with O_2
  If the O_2 supply (central gas supply or gas cylinder) fails, an alarm is issued.
– Supply of the patient with adequately oxygenated breathing gas
  If the breathing gas contains insufficient levels of O_2, an alarm is issued.
– Monitoring of the airway pressure and the expiratory minute volume
  Alarms are issued depending on the set alarm limits.
– Measurement accuracy of the O_2 measurement.
  Alarms are issued depending on the set alarm limits. If the O_2 sensor fails, an alarm is issued.

NOTE

In accordance with general safety standards, additional components are required for a complete anesthesia workstation.

Device combinations

The following text has been added:

This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the functional state of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices.

Device combinations approved by Dräger meet the requirements of the following standards (if applicable):

– IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
  – IEC 60601-1-2 (electromagnetic compatibility)
  – IEC 60601-1-8 (alarm systems)

Or:

– IEC 60601-1, 2nd edition (general requirements for safety)
  – IEC 60601-1-1 (device combinations)
  – IEC 60601-1-2 (electromagnetic compatibility)
  – IEC 60601-1-4 (software-controlled functions)
  – IEC 60601-1-8 (alarm systems)

Connections to IT networks

The following text has been added:

Data can be exchanged in an IT network using hard-wired and wireless technologies. An IT network can be any data interface (e.g., RS232) that is described in standards and conventions.

During operation, this device can exchange information with other devices by means of IT networks and supports the following functions:

– Display of waveforms and parameter data
– Signaling of alarms
– Service mode, access to logbooks

Information for connecting to an IT network

Prerequisites

This device must only be connected to the network by service personnel. The IT representative of the hospital must be consulted in advance.

The following documents must be followed:

– Accompanying documents of this device
– Descriptions of the network interface
– Description of the network-based alarm systems

Dräger recommends complying with IEC 80001-1 (risk management for IT networks with medical devices).

Serial interfaces

The following interfaces are supported:

– RS232 interfaces complying with EIA RS--232 (CCITT V.24/V.28) for the following applications:
  – MEDIBUS, MEDIBUS.X
  – Connections to medical devices from other manufacturers

Electrical requirements of connected devices and networks

The serial port is only appropriate for connecting devices or networks that have a nominal voltage on the network side of maximum 24 V DC and meet the requirements of one of the following standards:

– IEC 60950-1: Ungrounded SELV circuits
– IEC 60601-1 (as of 2nd edition): Exposed secondary circuits

CE 0123

Directive 93/42/EEC concerning medical devices

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